



# Information on JYNNEOS<sup>®</sup> (modified vaccinia Ankara – Bavarian Nordic, MVA-BN) vaccine

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## What is monkeypox?

Monkeypox virus is a DNA virus related to the virus that causes smallpox. Monkeypox is less severe than smallpox. Monkeypox can be spread from infected animals to people, or from person to person. Monkeypox does not spread easily between people. Transmission between people can occur through:

- close contact with rashes, blisters or sores on the skin
- body fluids, including respiratory droplets from coughing or sneezing (this is less common and usually only happens if there is prolonged face-to-face contact)
- contaminated objects such as linen and towels.

Monkeypox is usually not life-threatening. Infection with the monkeypox virus usually causes a mild illness and most people recover within a few weeks. Monkeypox can be associated with more significant clinical features such as painful rash/sores in the throat or rectum.

Some people can get severely unwell and suffer complications, and potentially death. People at higher risk of severe disease and complications with monkeypox include people with immunocompromise, young children and pregnant women.

Complications include secondary infection, scarring, sepsis (infection of the blood stream), pneumonia (lung infection) and encephalitis (inflammation of the brain).

## About the vaccine

JYNNEOS<sup>®</sup> (modified vaccinia virus Ankara – Bavarian Nordic, MVA-BN) is a vaccine used to prevent infection with smallpox and monkeypox viruses. It is also known as IMVAMUNE<sup>®</sup> and IMVANEX<sup>®</sup>.

The vaccine is made using weakened live vaccinia virus and cannot cause smallpox or monkeypox.

A complete vaccination course with JYNNEOS<sup>®</sup> requires two doses, given at least 28 days apart, by subcutaneous (under the skin) injection.

People at high risk of monkeypox virus infection who have received a smallpox vaccine dose more than ten years ago are recommended to receive only one dose of JYNNEOS<sup>®</sup>.

People who have had monkeypox virus infection during this outbreak are not recommended to be vaccinated at this time as they are likely to have immune protection from their infection.

There are no studies directly assessing the effectiveness of JYNNEOS® in people infected with the smallpox virus or the monkeypox virus. However, studies have shown that people given JYNNEOS® produced antibodies to a level expected to provide protection against smallpox.

Maximum protection occurs around 2 weeks after the second dose of this vaccine.

JYNNEOS® is most effective when it is used to vaccinate a person before they are exposed to monkeypox. JYNNEOS® may also be given to a person soon after they have been exposed to a monkeypox case, preferably as soon as possible. Vaccination within 14 days after exposure to a monkeypox case is expected to reduce severity of the disease.

JYNNEOS® is not registered for use in Australia and has not been formally assessed by the Therapeutic Goods Administration (TGA) but has been made available via a special emergency pathway under section 18A of the *Therapeutic Goods Act 1989 (Cth)*. JYNNEOS® is licensed in the United States of America for adults aged 18 years and older and the equivalent product with the same formulation and strength of JYNNEOS® is registered for use in adults in Europe as IMVANEX® and in Canada as IMVAMUNE®. All currently available [information](#) on the safety and efficacy of JYNNEOS® has been evaluated by the Australian Technical Advisory Group on Immunisation (ATAGI).

## Who can get this vaccine?

### *Individuals 18 years and older*

JYNNEOS® is indicated for use in adults aged 18 years and older at high risk for monkeypox infection.

### *Individuals under 18 years*

JYNNEOS® has not been formally studied in children aged under 18 years. However, there are clinical study data on safety in children of MVA (the active substance in this vaccine) which was also a vaccine component in a small number of childhood vaccines. ATAGI advises that vaccination with JYNNEOS® in children can be considered, especially for individuals in high-risk groups aged 16 years and older, after discussing the risks and benefits of vaccination with their vaccination provider.

JYNNEOS® has not been formally studied in people who are pregnant or breastfeeding. Based on animal studies, JYNNEOS® is considered safe to use in people who are pregnant or breastfeeding. However, vaccination should only be considered when the potential benefits outweigh any potential risk to the mother and baby.

## What you need to know before you receive the vaccine

You **must not** receive JYNNEOS® if:

- you have had a sudden life-threatening allergic reaction to a previous dose or to any ingredient of JYNNEOS® (active substance: modified vaccinia Ankara – Bavarian Nordic live virus; other ingredients: trometamol, sodium chloride; contains small amounts of chicken host-cell DNA, chicken protein, benzonase, gentamicin, and ciprofloxacin)
- you are unwell with a high temperature (>38.5°C). In this case, your vaccine provider will postpone the vaccination until you are feeling better.

Talk to your vaccine provider before receiving JYNNEOS® if you:

- have had anaphylaxis (severe allergic reaction) to any vaccine or medicine
- have had a known or possible exposure to monkeypox in the last 14 days
- have atopic dermatitis (eczema)
- are living with HIV or another condition or treatment leading to a weakened immune system
- are pregnant or breastfeeding
- have had a COVID-19 vaccine in the past month
- have had a previous smallpox vaccine dose ever
- have had a smallpox or monkeypox vaccine recently (e.g., overseas)
- have previously had monkeypox virus infection.

People who have previously had a smallpox vaccine, including any doses of JYNNEOS® may still get monkeypox if they are exposed to an infected person. If you develop any symptoms of monkeypox, you must still follow all health advice you are given by your state or territory public health staff.

Clinical studies suggest that people with weakened immune systems may have a lower immune response to JYNNEOS® compared to healthy individuals.

JYNNEOS is considered safe to use in people with atopic dermatitis (eczema) and in people with weakened immune systems.

People who have received one dose of JYNNEOS® (or equivalent vaccine) overseas should wait at least 28 days before they get a second dose of JYNNEOS®.

## What to expect after vaccination

As with any vaccine, you may have some side effects after receiving this vaccine. Most side effects are mild, short-lived and occur within a few days of receiving the vaccine.

There are no notable serious adverse events based on available data from clinical studies in over 7,800 people.

Common side effects reported in clinical studies after receiving JYNNEOS® vaccine include:

- injection site pain, redness, swelling or itch
- muscle aches
- headache
- fatigue
- nausea
- chills
- fever

People with atopic dermatitis (eczema) may be more likely to have side effects after vaccination compared to those without this condition.

Clinical studies show that there are similar levels of side effects experienced by people who have previously had a smallpox vaccine compared with those who have not.

JYNNEOS® may be given at the same time as other vaccines.

It is not known if JYNNEOS® is associated with a risk of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining of the heart). Spacing JYNNEOS® and a COVID-19 vaccine apart by several weeks may be considered for people with increased risk of myocarditis and/or pericarditis after mRNA COVID-19 vaccine, such as young adult males.

You should **seek medical attention** after vaccination if you:

- **Think you are having an allergic reaction. Call 000 if you experience severe symptoms, such as difficulty breathing, wheezing, or collapsing.**
- **Have chest pain, pressure or discomfort, irregular heartbeat, skipped beats or ‘fluttering’, fainting, or shortness of breath**
- **Are worried about a potential side effect or have new or unexpected symptoms**

Tell your health care provider if you have any side effects after vaccination that you are worried about. You or your vaccination provider should report adverse events to your state or territory health department or to the TGA. More information is available on the [TGA website](#).

You may be contacted by SMS or email in the week after you have received the vaccine to see if you have had any side effects, as part of vaccine safety surveillance.

## Australian Immunisation Register

The person giving your vaccination should record it on the Australian Immunisation Register (AIR). Collection of your personal information for this purpose meets the requirements of the *Privacy Act 1988 (Cth)*. You can view your vaccination record through your Medicare Online account via:

- Express Plus Medicare mobile app
- MyGov
- My Health Record (you can register for this with a Medicare number or an individual healthcare identifier).

Collection of your vaccination information on the AIR ensures that you have a complete vaccination record. This means you and your health care provider can keep track of vaccines you have received and when you are due for any subsequent doses. Your vaccination provider can also report other monkeypox or smallpox vaccines that you may have received overseas to the AIR.

## Further information

- [ATAGI clinical guidance on vaccination against monkeypox](#)
- [Australian Government Department of Health and Aged Care](#)
- [JYNNEOS® United States drug label](#)
- [European Medicines Agency IMVANEX product information and medicine overview](#)
- [ASCIA Guidelines: Vaccination of the egg-allergic individual - Australasian Society of Clinical Immunology and Allergy \(ASCIA\)](#)